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ABSTRACT

Regulations for the protection of human subjects have been introduced by the Federal government to try to mediate among the different special interest groups seeking or resisting regulations affecting the conduct of research. Educational researchers have been particularly resistant to regulations. The risks in conducting educational research are real, and the solutions are not yet provided. Educational research involving children presents some special problems which are being addressed by recent additions to the original regulations. Risks to children include overtesting, labeling, creating dependency upon the researcher, expecting or forcing continued participation, misusing findings, overusing research subjects, not identifying treatment, asking inappropriate questions, showing more concern for the data than for the subjects, and using dangerous techniques. The growing authority of institutional review boards, the increased power of gatekeepers of data, federal additions and interpretations to the regulations, and the increased number of related court decisions contribute to current problems and issues relating to the protection of research subjects. (Author/MH)

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The Federal Government and The Protection of Research Subjects: Implication for Educational Research

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Abstract

The Federal Government introduced regulations on the protection of human subjects in an effort to mediate among the different special interest groups seeking or resisting regulations affecting the conduct of research. Educational researchers have been particularly resistent to the regulations. The risks in conducting educational research are real and the solutions are not yet provided. Educational research involving children presents some special problems which are being addressed by recent additions to the original regulations. The growing authority of Institutional Review Boards, the increased power of gatekeepers of data, Federal additions and interpretations to the regulations and the increased number of court decisions contribute to current problems and issues relating to protection of research subjects.

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There is enormous resistence to Federal regulations concerning the protection of human subjects in educational research. This resistence is not only found in the general educational research community but is also found in educational sections of Federal agencies. Meeting after meeting has been held in which the case against such regulations has been made. The arguments are based on the proposition that educational research does not involve risk to subjects and because of no risk, no system for assuring protection of subjects is necessary or warranted. The discussions have, however, included some attempts to separate out educational research which should not be covered by the regulations and that which may need to be covered. One interesting subdiscussion has been whether or not educational research is part of behavioral research which was included under the 1974 protection of human subjects requirements. It suggests that if we can prove educational research is not behavioral research then no Federal regulations for the protection of subjects are necessary in educational research. The spuriousness of that argument does not need to be challenged any more than to point to it as an indication of the extreme effort being made to resist regulations. The effort is even more focused and intense when children are included as subjects in educational research, because added to regulations for the protection of the subjects are concerns about informed parental consent and informed child assent.

The resistence to regulations is understandable. Industries do not want to be regulated by environmental impact considerations. Television does not want to be regulated in amounts of violence shown or minutes per hour for commercials. Drivers do not want to be regulated by the 55 mile per hour speed limit. And most citizens do not want to be regulated on consumption of energy. Regulations are seen as restrictions to achieving goals of special interest groups which are legitimate and desired when considered from the perspective of industry,

television, drivers and consumers. Regulations are also seen as adding to the cost of achieving goals,and that is generally true.

Educational researchers, like most researchers, want to achieve their goals of knowledge and data in a free exploratory environment with a minimum of interference from any source. They, too,comprise a special interest group which achieves its sense of worth and also its livelihood from the special interest. Many of them see the regulations on protection of human subjects as infringing on their freedom to study and also as adding significantly to the time and costs of conducting research. They are right on the first count - infringement of freedom - primarily if they still see research subjects as theirs to do with as they professionally determine. How many researchers required their students to be available as subjects? How many researchers never thought of asking children or their parents if they were willing to be subjects? Schools, universities, institutions of correction, institutions for the handicapped, special physical or psychological conditions, all were seen as the domain of researchers and with more or less captive subjects. Some more recent indications of direct infringment on research freedom will be discussed later. As for added costs and time in conducting research,both are true. There is even some talk floating around of adding a line item to research budgets for malpractice insurance! But, let us look at how we arrived to the present situation on protection of human subjects and then identify current issues and problems.

Federal concern about research subjects

The Federal government supports most of the research being conducted in the nation. This fact has been true since the early 1960's and the amounts of money devoted to research increased steadily until the past few years when it has leveled off. There was pretty much a laissez-faire attitude toward researchers, relying heavily on the ethics of the various

professions to assure proper behavior in conducting research. But during the 1960's when research moneys for education, biomedical and behavioral sciences made quantum leaps and much of the research in education and other behavioral science affected large numbers of citizens, the picture began to change. Parent groups began to resist having their children or themselves as research subjects. Much of their resentment was about use of research data to place children in special classes, use of tests which seemed to mitigate against children from minority groups, lack of confidentiality of information or protection of privacy. Groups other than parents who are advocacy groups for citizens also resisted much of the research being conducted. Law suits abounded and many have not yet been resolved.

The Federal government responsed to the special interest groups and advocacy groups by acting as a mediator among the different groups. The Privacy Act of 1974 and the Family Education Rights and Privacy Act, a section (438) of The Educational Amendments Act of 1974, both responded to the public complaints. A further response was the National Research Act (P.L. 93-348) also passed in 1974. The Privacy Acts and the Family Rights Act must be considered when conducting research, but it is the protection of "subjects at risk" that is of primary concern in the National Research Act and for us here.

There are a number of questions which need to be addressed when considering the protection of subjects in research. They are:

1. who is a "subject at risk?"
2. who determines "subjects at risk?"
3. what are the special protection needs of children?
4. How is educational research involved?
5. What are the current issues and problems?

The remainder of this paper addresses these questions.

1. Who is a subject at risk?

The problem of establishing guidelines to protect research subjects begins with trying to define what it means to say a person is at risk within a research project. The definition of "subject at risk" is incorporated in the Department of Health, Education, and Welfare regulations of May, 1974 on the Protection of Human Subjects involved in grants and contracts supporting research, development and related activities. Section 46.103(b) of the regulations defines "subject at risk" as "any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service." That kind of definition requires interpretation and the Secretary of DHEW provided interpretation in a published statement in the June 28, 1976 Federal Register. This interpretation related specifically to welfare recipients, but in fact becomes an interpretation of the definition of "subjects at risk". The interpretation is quoted directly from the Federal Register:

. . . . . .

> the regulations were not, and have never been, intended to protect individuals against the effects of research and development activities directed at social or economic changes, even though those changes might have an impact upon the individual. More particularly, they were not designed to protect against possible financial injury, which may result from alteration in the price, availability, or conditions of eligibility for benefits or services offered under a governmental program.

The interpretation provides more examples of such research and then goes on to interpret the standard for measuring any departure from "established and accepted methods".

> The standard for measuring any departure from "established and accepted methods" with respect to activities designed to test the effect of social and economic change has traditionally been intended by the Department to include the range of experience of the average American in his daily life. Thus, with respect to work requirements for able-bodied welfare recipients, the standard for determining such a departure would be the experience of the average able-bodied American who must work to obtain his sustenance rather than the experience of most welfare recipients who do not work. Similarly, subjecting a group of people to a requirement that they report income for purposes of obtaining governmental benefits, or causing a lowering of their income, or requiring them to make some payment toward the cost of their medical care would not depart from the normal experiences which other Americans can expect to encounter in their daily lives, and would thus not constitute the type of departure from "ordinary and accepted methods" to which the regulations were intended to apply.
>
> Moreover, the regulations are not intended to protect individuals from the "ordinary risks of daily life". There are certain risks which may reasonably be expected to be encountered by anyone, for example, the risks inherent in having to make a decision as to how to allocate funds, or in deciding whether to meet certain conditions, such as performing work, which are required in order to obtain funds. The exposure to the risks which emanate from these choices does not constitute the type of situation against which the Department's regulations are designed to guard.

The question of defining "minimal risk" when children are involved in research was answered in the Federal Register, July 21, 1978, Parv V, DHEW, Protection of Human Subjects, Research Involving Children. The definition appears in Section 46.403(j) as follows:

> "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy children.

There has not been time for interpretation of that definition but the fact is, interpretations go only not only at the Federal level but at the institution where or out of which research is being conducted.

2. Who determines "subjects at risk?"

Institutions receiving Federal grants and contracts are interpreting definitions as they determine "subjects at risk." They cannot avoid doing so since each institution is required to address the problem. The 1974 regulations require that a review committee or group be established in each institution submitting a proposal for Federal funding of research. This committee or group increasingly referred to at the Institutional Review Board (IRB) is charged with the responsibility of reviewing the proposals to be submitted to determine if there are "subjects at risk." The committee must interpret the definition and make a decision. The institutions involved must fill out a form stating they have such a committee and must certify that each proposal has been reviewed and a decision made about whether research subjects are at risk or not. The review process is what is mandated by the regulations. However in the July 21, 1978, regulations concerning children, further guidelines are provided concerning what should be included in the review process. In the Summary section of the issuance are these guidelines:

> The Department of Health, Education, and Welfare (DHEW) is proposing regulations to implement the recommendations on research involving children of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Key provisions require that such research can be carried out only if the research methods are appropriate, the investigators competent, the facilities adequate, and the research procedures designed to contribute vitally to generalizable knowledge. Risks must be minimized, and the research performed in connection with necessary diagnosis and treatment wherever possible. Adequate provisions must be made to obtain the assent of the child and the consent or permission of the parents or guardians whenever there are necessary.

3. What are the special protection needs of children?

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established by the National Research Act (P.L. 93-348) and has provided leadership for stating policies and guidelines which become regulations to assure the protection of research subjects. Their work to date has been primarily with DHEW, although there is much evidence that their responsibility is to be widened to include all Federal executive departments. The two questions the Commission asks of DHEW components are these:

> Does your component of DHEW of any elements thereof conduct or support any biomedical or behavioral research involving human subjects:
>
> If such research is conducted or supported what policies and procedures are enforced to assure the protection of human subjects?

These questions provided the basis for the May, 1974 Regulations and did not address the special needs of children. The Commission had great difficulty addressing the problem of children as research subjects. In the Commission's May 6, 1976 Preliminary Draft of Children as Research Subjects, the following summary of the history and of the problem is stated:

> In 1964, the World Medical Association published its code of research ethics, the Declaration of Helsinki, which provides that "if (the subject) is legally incompetent the consent of the legal guardian should be secured". The Helsinki code was adopted in this country by the Society for Clinical Investigation, the American College of Physicians, the American College of Surgeons, and most importantly, the American Medical Association, thus providing support for the participation of children in research.
>
> The Institutional Guide to DHEW Policy for the Protection of Human Subjects, published in 1971, endorsed the Helsinki code and provided for the consent of an "authorized representative" of a subject who could not provide his

> or her own legally valid consent. The 1971 policy was converted into Federal regulation in May, 1974, more or less as originally written, except that the current regulations require that anyone consenting on behalf of another be a "legally authorized representative". This is defined in the regulations as "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject's participation in the particular activity or procedures". In November, 1973, the Department proposed additional policy for the protection of children as research subjects, including a provision for the consent or agreement of children age 7 or over; however, the proposals have not been developed into rulemaking, as yet.

The problems were both legal and ethical. What are the legal rights of children in consenting to participate in research? What are their legal rights when the research is therapeutic and when it is non-therapeutic for the particular child? What moral responsibility does a child have to be used as an instrument to provide empirical evidence necessary to the expansion and validation of human knowledge? What is the role of parental consent? Who can speak for institutionalized and incompetent children?

Answers to these questions vary greatly, as the Commission learned from its April 9, 1976, public hearing on the issue of research involving children. Some experts stated a child should give consent at age 7. Others scoffed at this reflecting naive notions about generalizable abilities of seven year olds. Some stated that in therapuetic research the child's consent should not be necesssary while others felt the child should be able to give consent. Some stated that the individual rights of children take precedence over social obligations while others stated exactly the opposite view. Some experts stated that no institutionalized minors should be research subjects while others stated that, with proper third party approval, such subjects should be part of research. The whole notion of informed consent was raised with no clear answers. One expert made four comments about informed consent which highlighted the problems: (1) it has many levels of meaning for different kinds of children; (2) it is a continuing

process and not a one time affair; (3) it is improper and meaningless to propose an age at which a child may give informed consent, since there can be no single criteria; and (4) we must question the purpose of informed consent.

The resolution of these problems appeared in the July 21, 1978 Federal Register on Research Involving Children. The Institutional Review Board is charged with carrying out the new Guidelines. Because these Guidelines directly affect research design as part of the protection of subjects, the entire section is presented.

> (a) In addition to all other responsibilites under this part, each Institutional Review Board (Board) shall review research covered by this subpart. It may approve the research only if it finds that:
>
> (1) The research methods are appropriate to the aims of the research;
>
> (2) The competence of the investigator(s) and the quality of the research facility are sufficient for the conduct of the research;
>
> (3) Where appropriate, studies have been conducted first on animals and adult humans, and then on older children before involving very young children;
>
> (4) Risks are minimized by using the safest procedures consistent with sound research design and by using procedures performed for the examination, diagnosis, or treatment of the particular subject whenever appropriate and feasible;
>
> (5) Adequate provisions are made to protect the privacy of children and their parents, and to maintain the confidentiality of data. For example, data may be disclosed to authorized personnel and used for authorized purposes only; data should be collected only if they are relevant and necessary for the purposes of the research and analysis; data should be maintained only as long as they are necessary to the research or to benefit the children; and all data should be maintained in accordance with fair information practices;
>
> (6) The criteria for subject selection are appropriate for the research aims and will permit the selection of subjects in an equitable manner, avoiding overuse of any one group of children based solely upon administrative convenience or availability of a population;

(7) Where appropriate, adequate provisions are made for involving a parent, guardian, or advocate in the conduct or monitoring of the research, for example, in situations in which the Board finds the subjects to be incapable of assenting and the research involves more than minimal risk or more than minimal discomfort to these subjects;

(8) Adequate provisions are made for monitoring solicitation of assent and permission, as, for example, through participation by Board members or by advocate in the actual solicitation process, either for all subjects or for a sampling of subjects; and

(9) The conditions of all applicable subsequent sections of this subpart are met.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution sponsoring the Board shall certify to the Secretary, in such manner as the Secretary may require, that the duties of the Board under this subpart have been fulfilled.

4. How is Educational Research involved?

Children are likely subjects in educational research and questions of what kinds of research involve risk and what kinds do not must be addressed. The risks to children in educational research may be psychological, sociological, physiological and/or academic. Risks to children incude the following:

a. Overtesting. Many children are tested for too long a time at one session or over too much time. Their physical limitations may be ignored and they may be reluctant to complain of fatigue because they are part of a study. The overtesting is frequently tied in with the desire of the researcher to validate and standardize tests and to take advantage of an available population which is part of a research project.

b. Labelling. While it is necessary to give names to conditions and diagnoses, it is not necessary or accurate to stereotype behavior from labels. Children from minority groups and families with low incomes are particularly likely to be stereotyped and stigmatized. Also, children labelled as mentally handicapped may easily be

stereotyped and stigmatized.

c. Creating dependency. Some research provides services to children which encourages dependency on the providers. This may be either an integral or peripheral part of the research. It may even be a desired outcome, but what happens when the research ends? Not all researchers address this problem.

d. Expecting or forcing continued participation. Many children are fearful of withdrawing from the project. They like to keep their commitment and do not like to be different from the children who stay in the research project. They also feel guilty. These feelings may prevent them from withdrawing even when they are disturbed by the project or have nightmares about it.

e. Misuse of findings. The misuse of research findings takes many forms; one is omission and the other commission. The misuse of omission occurs when the lack of feedback on the research findings leaves the involved subjects anxious about the outcome or unable to benefit from the findings. The misuse of commission occurs when findings are made available selectively to support prejudices or when findings are made available without respect for the privacy rights of the subjects.

f. Overuse of research subjects. Many children, particularly those who meet low income and underachievement criteria, are placed in so many research projects that they are isolated from the school's mainstream, both academic and social, and have problems with re-entry into the mainstream. There are few records of the scope, both in numbers of research programs and years of such programs, to determine the potential harm or indeed, the accrued benefits.

g. Unidentified or unusual treatment. Some researchers do not want children to know about the treatment or technique being used in a research project. This is especially true in behavior modification techniques which rely on an unawareness on the part of the subject. Unusual treatment may include techniques or subject matter that exposes children to moral and cultural shock.

h. Inappropriate questions. Even if research findings are not misused, there are many questions which are inappropriate. These questions include those asking about peer and family relationships, one's sense of failure or success, one's experiences with drugs or delinquency. As a matter of fact, recent research involving self-reports of youth were terminated because youth were in fact being asked to provide self-incriminating information.

i. Attitudes of researchers. There are researchers who feel their commitment to generating knowledge should take precedence over concern for the effects of the research on the subjects. They want the data, and they do not want any contamination of the data by loss of subjects, restrictions in procedures, involvement of subjects in data use, etc. There are other researchers who already hold biases and prejudices about certain populations and conduct their research to, in fact, support the biases and prejudices.

j. Dangerous treatment. The use of electric shock, drugs, psychological and other biomedical techniques in research with children in preschool and school settings has already brought many responses from the public. These responses are usually accompanied by evidence of damage. The Secretary's interpretation of "Subject at Risk" referred to above, incorporates the special concern for dangerous treatment.

> The types of risk situations against which the regulations were designed to protect are suggested by the areas of concern which were addressed in the legislative hearings held in conjunction with the enactment of section 474 U.S.C. 2891-3 (added by P.L. No. 93-348), which forms part of the basis for the Departmental regulations at 45 CFR Part 46, and in the preambles to the proposed and final regulations at 45 CFR Part 46. The subjects addressed included the use of FDA-approved drugs for any unapproved purpose; psychosurgery and other techniques for behavior control currently being developed in research centers across the nation; use of experimental intrauterine devices; biomedical research in prison systems and the effect of that research on the prison social structure; the Tuskegee Syphilis Study; the development of special procedures for the use of incompetents or prisoners in biomedical research; and experimentation with fetuses, pregnant women, and human in vitro fertilization. The regulations were intended, and have been uniformly applied by the Department, to protect human subjects against the types of risks inherent in these types of activities.

The interpretation is broader than for children alone, but certainly includes them.

The question of Guidelines for educational research was addressed in the July 21, 1978 Federal Register issue on Research Involving Children. Under the section, Should Some Research Be Exempted From These Regulations? The issue of educational research is addressed. The section is included in full so that the nature and status of the issues are clear.

> The issue of the scope of the Department's policies on protection of human subjects has been raised in the context of the children's regulations, because of the specific impact these regulations would have on educational research. However, the applicability clause in the proposed children's regulations is simply patterned after the clause which currently appears in the basic Department regulations on protection of human subjects in 45 CFR part 46. Hence, to the extent the children's applicability clause is too broad, the same would probably be true with respect to the clause in the basic regulations.
>
> Those who object to the current, broad applicability clause in part 46 point out that it requires establishment of Boards by all organizations which apply to the Department for any support for research involving human subjects. In social and educational research, it is said that the research rarely presents any significant risk to the subjects. In these fields, many of the applicants are small organizations for which it is a substantial administrative and financial burden to establish Boards to satisfy part 46. Often the research is of a type that has undergone substantial

review within the Government before it can be undertaken (e.g., certain types of survey research which must be reviewed by the Office of Management and Budget under the Federal Reports Act).

Another concern which has been raised about the scope of the regulations pertains to large scale, innovative, service delivery programs. Technically, it might be argued that a State or local subdivision may be engaged in research when it introduces an innovative modification into a service delivery programs. Once the decision is made through normal governmental processes to adopt the innovation, it is said that Boards should not have the option to veto this decision, and individuals should not have the discretion to opt out of those aspects of the program that are disadvantageous to them.

In view of thse objectives, the Department will consider whether, as part of the overall revision of part 46 (which will take place once all the Commission's recommendations are received), the applicability clause of the basic regulations and all other regulations in part 46 should be narrowed.

Among the types of activities which may be considered for exemption from part 46 are the following:

1. Survey research, particularly where the survey form must be cleared by the Office of Management and Budget.

2. Observational research, where the researchers simply observe subjects engaged in their normal day-to-day activities.

3. Achievement and aptitude testing.

4. Research involving solely the review of already existing records.

5. Participation in instructional and other programs carried out in the normal educational setting, where the program is generally similar to other programs in the school curriculum and has been approved by a local school board or parent advisory group.

6. Research designed to study on a large scale the effects of proposed social or economic change.

7. Research designed to study on a large scale methods or systems for the delivery of or payment for social or health services.

The Department welcomes comment as to the appropriateness of narrowing the scope of part 46, through exempting some or all of the above categories of research from the regulations. The Department would also be interested in suggestions as to other categories which should be considered for exemption. Wherever possible, information and data should be submitted in support of comments.

> To the extent some categories of research are exempted from part 46, the Department is also considering whether other protections should be developed to cover these categories and, if so, what these should be. Commenters who propose narrowing part 46 may wish to address these issues as well.
>
> In connection with this reconsideration of the scope of part 46, each Principal Operating Component of the Department will be developing the capacity to review protections for human subjects, as part of their decision-making processes.
>
> Notice is given that it is proposed to make any amendments that are adopted effective upon publication in the Federal Register.

These July 21, 1978 regulations are still classified as Proposed Rules and responses may be made by those persons so desiring. However, as these regulations already reflect earlier responses, there are not likely to be many more changes.

The important thing to note is the direction regulations are taking to increasingly refine the limits of research and the responsibilities of Institutional Review Boards. The facts are even more complex than presented. The Privacy Act and the Family Education Rights to Privacy Act and the Freedom of Information Act each needs to be examined as it affects educational research. Then there is the Committee on Evaluation and Information Systems (CEIS) of the Council of the Chief State School Officers which, in cooperation with the National Center for Educational Statistics, determines what data from the schools may be made available to administrators and researchers. In addition to these is the Office of Management and Budget (OMB) which also claims some authority in determing what data may be gathered. The relationship between CEIS and OMB has been cordial, with OMB accepting the recommendations of CEIS on what data might be gathered and what instruments might be used. That relationship was terminated as a result of the Educational Amendments of Fiscal Year 1978 in favor of a Federal Education Data Access Committee (FEDAC) which permits FEDAC to make determinations without any involvement of OMB.

At some point each of these Acts, Amendments and Committees must address the protection of human subjects as well as the Institutional Review Boards. As a result a number of current issues emerge relating to educational research and the protection of human subjects. These issues need fuller discussion within the research community and among the involved groups; but pointing out the high lights of the success may be useful for the present discussion.

5. What are the current issues and problems?

The current issues and problems concerning the protection of human subjects in educational research may be organized around five questions. Each is presented with the highlights of the issue identified.

a. What is the extent of authority the IRBs should have?

Researchers are complaining that they have too much authority and are increasingly becoming involved in research design issues.

The Federal Government gives increasing authority to the IRBs, including determination of "appropriate" research design.

IRB's are seen as involving the local institution and community in protecting subjects in research; however there are no clear patterns of local and community involvement at any phase of the deliberations.

b. Who is or should be the gatekeepers for gathering research data?

Many researchers complain that the Chief State School Officers are guarding access to data and preventing access for political rather than research reasons.

Many parent and child advocacy groups complain that their views on access to data or participation in research are not being honored by CEIS.

Other critics point out an apparent conflict of interest within the Chief State School Officers; their Council can bid on

contracts to gather data and their CEIS organization, funded partially through NCES, is the gatekeeper for educational data.

Questions about the relationship between the IRB's and CEIS are being raised where they have the protection of subjects as a common concern.

c. Where are the professional associations in the protection of subjects in educational research?

Professional organizations like the American Psychological Association, the American Medical Association, AERA and the National Education Association are critized for not being very visible in the discussions on the protection of subjects in educational research.

Some researchers feel that the professional codes of ethics do not reflect changes determined by the new systems of protection of subjects.

Other critics point out that ways to avoid the new regulations seem of greater interest to professional groups than corporation, accommodation or alternatives.

d. What should be the role of the courts in determining and interpreting protection of subjects?

Critics point out that the more courts are asked to clarify definitions and responsibilities the more IRB's, professional groups and others relinquish their authority.

Many researchers point out that the more researchers see the issue of protection of subjects as a legal one rather than as an ethical and professional one, the more they lose control of their own profession.

e. What is the response of educational researchers to the request for comment on regulations protecting subjects?

Some claim the researchers are more interested in finding ways to get around the regulations than to respond to them.

Many feel the individual researchers are powerless but do not urge their professional organizations to address the issues for them.

Some researchers feel they should find, direct and clear ways to assure subjects of protection of privacy, informed assent and consent, and protection from harm.

The issues and problems concerning protection of subjects in educational research are going to become more complex over time. More groups are involved, more structures are developing, more authority is being assigned and more conflicts are inevitable. It seems time to get back to the purpose of the protection of subjects and then to examine what we are allowing to happen in light of the essence of the charge to protect.